K111103

Section 5: 510(k) Summary

JAN - 5 2012

510(K) Summary

General Information:

Data:	*April 19, 2011*
Applicant:	*RF Co., Ltd.*
	3 Nakagosho, Nagano-shi, Nagano, 380-0935, JAPAN
Contact Person:	*Daisuke Tanaka*
Telephone:	*81-26-225-7744*
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Proposed Device:

Trade Name:	*RF System lab.*
Device Name:	*Digital X-Ray Imaging System, NAOMI-DPX-D100*
Classification Name:	*90MQB, Solid State X-ray imager*

Predicate Device:

RF System.lab. :	*NAOMI (K062376)*
Schick Technologies, Inc. :	*CDR-PAN MODEL 4700 (K982661)*
Signet Radiology, Inc. :	*Signet DXIS (K983283)*
Trophy Radiologie :	*DIGIPAN / DPI (K012514)*

Device Description:

The NAOMI-DPX-D100 provided digital image capture for conventional film/screen systems. It is intended to replace the radiographic film/screen systems.

The x-ray photons incident to the NAOMI-DPX-D100 are detected and converted into the light photons at the scintillator. The light photons are detected and converted into the electrical signal at the CCD. NAOMI-DPX software captures and displays the image.

Indications for Use:

The NAOMI-DPX-D100 provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace the radiographic film/screen systems in panoramic dental diagnostic procedures.

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Comparison to predicate:

The use of the NAOMI-DPX-D100 is the same as predicate devices. The value that evaluate image quality is different from NAOMI, however, most of the specifications are the same or better than NAOMI.

Conclusion:

The performance data demonstrate that NAOMI-DPX-D100 is as safe and effective as the predicate devices (CDR-PAN MODEL4700, Signet DXIS and DIGIPAN DPI). It is opinion of RF Co.,Ltd. strongly believe that the NAOMI-DPX-D100 described in this submission is substantially equivalence to predicate device (NAOMI).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Koji Kubo
Manager
RF CO., Ltd.
6-5-3 Beaune Homkomagome 2F
HOMKOMAGOME BUNKYO-KU
TOKYO 113-0021
JAPAN

AUG 23 2013

Re: K111103
Trade/Device Name: Digital X-Ray Imaging System, NAOMI-DPX-D100
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH, EHD, and MQB
Dated: December 7, 2011
Received: December 8, 2011

Dear Mr. Kubo:

This letter corrects our substantially equivalent letter of January 5, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K111103

Device Name: Digital X-Ray Imaging System, NAOMI-DPX-D100

Indications for Use:

The NAOMI-DPX D100 is indicated for use in acquiring Panoramic radiographic images at the dento-maxillofacial region. The image generated is displayed on a computer monitor. It is intended to replace radiographic film/screen system in dental diagnostic procedures

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K111103